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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|------------------------|-----------------------|------------------|
| 09/866,248   | 05/25/2001  | Christophe P.G. Gerald | 1795/57155-AA JPW/BJA | 6169             |
| 45821  | 7590        | 03/24/2005             | EXAMINER              |                  |
| SYNAPTIC PHARMACEUTICAL CORPORATION<br>ATTENTION: STEPHEN G. KALINCHAK, LEGAL<br>215 COLLEGE ROAD<br>PARAMUS, NJ 07652 |             |                        |                       | MURPHY, JOSEPH F |
| ART UNIT   |             | PAPER NUMBER           |                       |                  |
|  |             | 1646                   |                       |                  |

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                  |               |
|------------------------------|------------------|---------------|
| <b>Office Action Summary</b> | Application No.  | Applicant(s)  |
|                              | 09/866,248       | GERALD ET AL. |
|                              | Examiner         | Art Unit      |
|                              | Joseph F. Murphy | 1646          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 183-191 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 183-191 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |



## **DETAILED ACTION**

### ***Formal Matters***

Claims 183-191 are pending and under consideration.

### ***Response to Amendment***

The objections to the claims have been obviated by Applicant's amendment and are thus withdrawn.

New issues are set forth below.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 183-191 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6, wherein the compound causes an increase (or decrease) in the level of inward chloride current or Inositol phosphate release, does not reasonably provide enablement for methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6 wherein the compound causes an increase (or decrease) of NPFF receptor activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6 wherein the compound causes an

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increase (or decrease) of NPFF receptor activity. This method is not enabled because the specification is not enabled for the full scope of NPFFF receptor activity. The term "NPFF receptor activity " is not defined by the claim, but give no definition of what this activity is. Various biological activities can be attributed to a polypeptide. For example, "activity" could constitute transportation throughout a cell, alteration of tertiary structure due to changes in pH, ligand binding, or modulation of second messenger effect, etc. 'Activity' could also be referring to the ability of the polypeptide to stimulate antibody production. The Specification teaches methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6, wherein the compound causes an increase (or decrease) in the level of inward chloride current or Inositol phosphate release. Although the specification outlines art-recognized procedures for measuring other activities, this is not adequate guidance as to the nature of activities that may be measured, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

Due to the large quantity of experimentation necessary to measure the large number of possible activities recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 183-191 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 183-191 are vague and indefinite in the recitation of the term "NPFF receptor activity". The term "NPFF receptor activity" is not defined by the claim, and gives no definition of what this activity is. Various biological activities can be attributed to a polypeptide. For example, "activity" could constitute transportation throughout a cell, alteration of tertiary structure due to changes in pH, ligand binding, or modulation of second messenger effect, etc. 'Activity' could also be referring to the ability of the polypeptide to stimulate antibody production.

Claim 186 recites the limitation "the first" in subsection (a). There is insufficient antecedent basis for this limitation in the claim.

Claim 186 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: that the second compound is known to bind the NPFF receptor.

Claims 183-191 recite the limitation "the mammalian NPFF receptor" in subsection (a). There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
March 14, 2005

*Joseph F. Murphy*  
JOSEPH MURPHY  
PATENT EXAMINER